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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,526	07/11/2003	Frits Jacobus Fallaux	2578-3833. 9US	5055
24247	7590	03/01/2006	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			PRIEBE, SCOTT DAVID	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,526

Applicant(s)

FALLAUX ET AL.

Examiner

Scott D. Priebe, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,10,11,16 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,10,11,16,21,22 and 25 is/are rejected.
- 7) ☒ Claim(s) 23 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20060106.
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. attached.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The Bout declaration under 37 CFR 1.132 filed 1/30/06 is sufficient to overcome the rejection of claims 1, 3-7, 9-11, 16, and 21-24 under 35 U.S.C. 102(f) in the part based upon US Pat. Nos. 6,340,595; 6,395,519; 6,413,776; 6,447,768; 6,670,188; 6,869,794; 6,878,549; and 6,855,544; and US applications 10/002,750; 10/036,949; 10/432,105; 10/494,140; 10/497,832; 10/512,589; 10/644,256; 11/039,767; and 11/083,590. As stated in the declaration, the instant invention was jointly invented by declarant and the other instant co-inventors (§ 3), and further development of this invention by others with or without inventor Bout resulted in subsequent inventions presented in the later filed applications (§§ 9 and 10). None of the later filed applications claim the instantly claimed subject matter itself; instead, all of them claim methods that use the conflicting subject matter, e.g. PER.C6 cells, or products that were made with the conflicting subject matter, which is consistent with the declaration.

The rejection under 35 U.S.C. 102(f) with respect to US 6,395,519 is withdrawn since Applicant has filed a petition to correct the inventorship of the patent by removal of Schouten as an inventor.

Double Patenting

The terminal disclaimer filed on 1/30/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any U.S. patent issuing from U.S. Application Nos. 10/432,105; 10/494,140; 10/497,832; 10/512,589; 10/644,256; 10/850,140; 11/039,767; 11/083,590; 10/038,271; and 11/134,674 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The terminal disclaimer filed on 1/30/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. Nos. 6,340,595; 6,395,519; 6,413,776; 6,447,768; 6,670,188; 6,869,794; 6,878,549; and 6,855,544 has been reviewed and is NOT accepted. The assignee has not established its ownership interest in the '595 and '776 patents, in order to support the terminal disclaimer. There is no submission in the record establishing the ownership interest by either (a) providing documentary evidence of a chain of title from the original inventor(s) to the assignee, or (b) specifying (by reel and frame number) where such documentary evidence is recorded in the Office (37 CFR 3.73(b)). Current records at the PTO indicate that the '595 and '776 patents are currently assigned to Galapagos Genomics N.V., not Crucell Holland B.V. Applicant's attorney indicated that the listing of these two patents was inadvertent, and a proper terminal disclaimer over the other patents would be filed. The substitute terminal disclaimer was received on 2/16/06.

The terminal disclaimer filed on 2/16/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. Nos.

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6,395,519; 6,447,768; 6,670,188; 6,869,794; 6,878,549; and 6,855,544 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claims 1, 3-7, 16, and 21 remain and claim 25 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-22 of copending Application No. 10/002,750 for the reasons of record set forth in the Office action of 8/29/05. Since the '750 application issued as US 6,974,695, the rejection is no longer provisional.

Applicant's arguments filed 1/30/06 have been fully considered but they are not persuasive. Applicant indicates that a terminal disclaimer over the '695 patent has been filed (page 31). However, no such terminal disclaimer has been received. Applicant's statement is therefore taken as an indication that a terminal disclaimer will be filed to overcome this rejection.

Claims 1, 3-7, 10, 11, 16, and 22 remain and claim 25 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over: claims 43 and 44 of U.S. Patent No. 6,340,595 and claims 7, 32, and 35 of U.S. Patent No. 6,413,776 for the reasons of record set forth in the Office action of 8/29/05.

Claims 1, 3-7, 16 and 21 remain and claim 25 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 67 and 95 of copending Application No. 10/036,949 for the reasons of record set forth in the Office action of 8/29/05. The '949 application has been allowed, and the issue fee has been paid. Upon issuance of the '949 application, this rejection will no longer be provisional.

Applicant's arguments filed 1/30/06 have been fully considered but they are not persuasive. Applicant argues that PCT/NL96/00244 was published Jan. 3, 1997, before the earliest priority date for the '595 and '776 patents. US 5,994,128 is a 371 of this PCT, and the instant application depends directly from the '128 patent. Applicant argues that since the PCT was published prior to the effective filing date of the '595 and '776 patents, their claims were and are patentable over the instantly claimed subject matter and therefore patently distinct from the instantly claimed subject matter. In response, the issue is not whether the claims of the '595 and '776 patents are non-obvious over or patently distinct from the instantly claimed subject matter, but rather the converse, whether the instantly claimed subject matter is obvious over the claims of the '595 and '776 patents. The subject matter of the claims of the patents are embraced by the instant claims, i.e. the instantly claimed subject matter is "anticipated" by the claims of the '595 and '776 patents. It is acknowledged that the "obviousness" here is only one way; the claims of the '595 and '776 patents are not obvious over the instant claims.

Applicant argues that if the instant application is issued, the patent would expire before the '595 and '776 patents, and thus there is no possibility for a 'time-wise' extension of monopoly. In response, the judicially created doctrine serves two purposes. The first is to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent, which, as Applicant points out, is not possible in this case. However, the second purpose is to prevent possible harassment by multiple assignees. This possibility certainly exists here since the '595 and '776 patents are not commonly assigned with the instant application.

Applicant also argues that the '595 and '776 patents are not "prior art" and that using the ODP doctrine to "back in the rejection cannot be a correct application of the doctrine". In

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response, whether the instant application has an earlier effective filing date than the patents is irrelevant to the ODP doctrine, see MPEP 804.

Applicant points out that under 35 USC 121, when a restriction requirement is imposed between two inventions, a divisional application with claims limited to a non-elected invention may not be rejected under ODP over an application with claims limited to the originally elected invention or a different non-elected invention. Applicant then proceeds to speculate that had the claimed subject matter of the '595 and '776 patents been present in the instant application it would have been restricted from the instantly claimed subject matter, and explains why it would have been restricted. In response, no such restriction requirement was ever made, so the prohibition under 35 USC 121 is not applicable here. See MPEP 804.01, particularly situation (A) in the list of situations where the provisions of 35 USC 121 do not apply. Also, what matters here is solely whether the subject matter of the instant claims is obvious (or anticipated) over that of the patents (one-way test), not whether the claimed subject matter of the patents is also obvious over the instant claims (two-way test), as addressed below.

Applicant argues (pages 15-17) that the fact that the '595 and '776 patents share a common inventor (Bout) with the instant application is mere coincidence; if the subject matter of the patents shared no inventor with the instant application, no ODP rejection would be made; the common inventor no longer has any rights in either patent or in the instant application; if ODP rejections such as the present situation were justified, it would have severe impact on the industry in general because it is not uncommon for inventors to be involved in making inventions with different employers, and incorporating earlier inventions into later inventions; and justification of the ODP rejection based on harassment by multiple assignees should be made

only upon the narrow interpretation of “the same invention”. In response, these arguments are directed to reasons why the doctrine of ODP should be modified, and are not reasons why the instant rejection is improper. The Examiner does not have the authority to overlook ODP in view of what may or may not be perceived as inconvenient or unfair consequences of the current ODP public policy.

Applicant argues (Reply, page 17) that since the Federal Circuit has sanctioned the practice of filing an application for the purpose of obtaining the right to exclude a competitor’s product from the market, and the instant application was filed to cover potential products of competitor’s, as sanctioned by the court, then the “two-way” test should be applied in the instant application. Applicant also argues that since ‘595 and ‘776 patents were filed after the instantly claimed subject matter was made public, the “two-way” test should apply. In response, two conditions must be met in order for the “two-way” test of obviousness to be applied in an ODP situation where the subject application is an earlier filed application with respect to the conflicting patent or copending application. Here, “earlier” application means the subject application has an earlier effective filing date, rather than an earlier actual filing date. First, Applicant could not have filed the claims in a single application. Second, there was an administrative delay in the prosecution of the earlier filed application. See MPEP 804, subsection B.1.(b). Neither of Applicant’s reasons are relevant to the two conditions required for applying the “two-way” test.

Applicant (Reply, pages 17-18) points out that applicants are encouraged to claim all inventions that are disclosed in an application to avoid dedicating to the public that which is not claimed, and argues that that is what Applicant is doing here, and the “two-way” test should

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apply. In response, Applicant's point here is unclear; the conclusion does not follow from the argument. Applicant had filed several applications with a common relationship to the instant application through US 5,994,128 prior to the filing of the '595 and '776 applications. Of these, the '128 patent and US Pat. Nos. 6,033,908; 6,265,212; and 6,306,652 all were issued before the issuance of either the '595 and '776 patents. Applicant has presented no evidence that they were prevented from including the instant claims in any of these earlier applications. Applicant chose not to present the instant claims in one of these earlier applications.

It is acknowledged that the first requirement for applying a "two-way" test is met here. Applicant could not have claimed the subject matter of the '595 and '776 patents. First, the claimed subject matter of the '595 and '776 patents is not disclosed in the instant application, and, according to the Bout declaration of 1/30/06, was not invented by the instant inventors.

Applicant argues that the analysis set forth in *In re Braat*, 19 USPQ2d 1289 (Fed. Cir. 1991) is applicable to the instant rejection. In response, Applicant misapplies this decision. Briefly, the court determined that the claims of Dil could not have been presented in the Braat applications, i.e. the Braat applications met the first requirement for applying a "two-way" test for ODP. Although Applicant notes that the "court determined that it was not Braat's fault that the claims of the Dil patent issued first, the arguments de-emphasize this point. The court more explicitly indicated in *In re Emert*, 44 USPQ2d 1149, 1152 (Fed. Cir. 1997) that application of the two-way test in *Braat* was appropriate because two conditions were met: the claims of Dil could not have been presented in the Braat applications *and* because "applications for basic and improved patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the applicant does not have complete control," citing *Braat* at 1292,

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i.e. Braat's application's also met the second requirement for applying the "two-way" test, i.e. administrative delay in prosecution by the PTO over which Braat had little control.

However, nowhere in the reply does Applicant argue, much less provide evidence that, the issuance of the '595 and '776 patents prior to the instant application was due to administrative delay on the part of the PTO. In fact, the instant application was filed on 7/11/03, which was after the issuance of both the '595 and '776 patents. Prior to filing the instant application, Applicant had already been issued US 5,994,128, from which the instant application descends, and US Pat. Nos. 6,033,908; 6,265,212; 6,306,652; and 6,395,519, which also descend from the '128 patent, prior to the issuance of the '595 and '776 patents, and each of the '128, '908, '212, '652, and '519 patents have been terminally disclaimed in the instant application in response to ODP rejections. There is no evidence of record that the PTO prevented Applicant from including the instant claims into any of these earlier patents during their prosecution. This earlier issuance of patents over which the instant claims were obvious under ODP doctrine shows that there was no administrative delay by the PTO that caused earlier issuance of applications with later effective filing dates. The instantly claimed subject matter could have been claimed and been issued in any of these earlier patents. Applicant has been solely in control of the delay in prosecution of the instant claims. Consequently, the instant claims need only be obvious over those of the '595 and '776 patents to be ODP, i.e. the "one-way" test is applicable here, not the "two-way" test.

Applicant's remaining arguments deal with whether the claimed subject matter of the '595 and '776 patents meets the "two-way" test for obviousness. It is acknowledged that the claimed subject matter of the '595 and '776 patents is not obvious over the instant claims, and

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that the “two-way” test would fail if it were applicable. However, these arguments are moot since the ‘two-way’ test for obviousness is not required here for the reasons given above.

Allowable Subject Matter

Claims 23 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

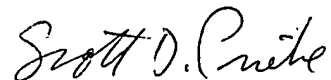
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633